



TW

Atty. Docket No. TAK03 P-331

CERTIFICATE OF MAILING

I hereby certify that this paper, together with all enclosures identified herein, are being deposited with the United States Postal Service as first class mail, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date indicated below.

December 11, 2006

Date

Deborah A. Clark

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Yasuaki Ogawa et al.
Appln. No. : 10/588,834
Filing Date : August 9, 2006
For : PROTEIN SUSTAINED-RELEASE MICROPARTICLE
PREPARATION FOR INJECTION AND PROCESS FOR
PRODUCING THE SAME

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97(b)

Pursuant to 37 CFR §§1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO-1449. This Information Disclosure Statement is being filed more than three months after the date of entry of the national stage in an international application but, to the undersigned's knowledge, before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed foreign patent documents and non-patent literature are attached.

As the Office has waived the requirement under 37 CFR §1.98(a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication, copies of the listed U.S. patents and each U.S. patent application publication documents are not included with the submission of attached Form PTO 1449. Applicants respectfully request that the Examiner consider the listed documents and evidence that consideration by making appropriate notations on the attached form.

English translations of the abstracts of the non-English documents are enclosed.

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The listed documents were cited in the International Search Report which issued from a corresponding PCT Patent Application. A copy of the International Search Report is included herewith. The International Search Report is not a reference, and Applicants do not necessarily subscribe to any of the statements contained therein.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitutes "prior art." If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

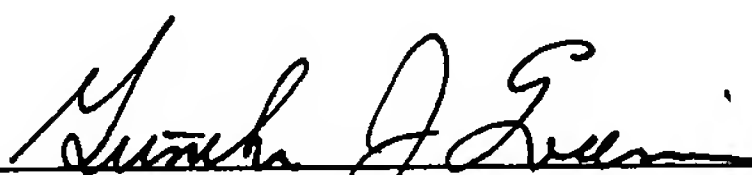
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 16-2463.

Respectfully submitted,

December 11, 2006
Date

GJE/dac



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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 2-32) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT Use several sheets if necessary)	ATTY. DOCKET NO.	SERIAL NO.
	TAK03 P-331	10/588,834
	APPLICANTS Yasuaki Ogawa et al.	
	FILING DATE	GROUP
	August 9, 2006	



U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPRO- PRIATE
	5 6 5 6 2 9 7	08/12/97	Bernstein et al.			
	5 6 4 8 0 9 7	07/15/97	Nuwayser			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
					Y N
	JP2004 0 7 5 6 6 2	03/11/04	Japan		X abstract
	JP2004 3 0 7 3 9 8	11/04/04	Japan		X abstract
	WO 05/ 0 2 5 5 4 2	03/24/05	PCT		X abstract
	JP 3 0 6 8 5 1 1	03/25/91	Japan		X abstract
	JP 6 2 9 3 6 3 6	10/21/94	Japan		X abstract
	JP10 5 1 1 9 5 7	11/17/98	Japan		X abstract
	JP10 2 3 1 2 5 2	09/02/98	Japan		X abstract

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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					Y N
	JP2005 0 0 8 5 4 5	01/13/05	Japan		X abstract
	WO 04 1 1 2 7 5 1	12/29/04	PCT		X abstract
	JP2002 3 4 8 2 3 4	12/04/02	Japan		X abstract
	JP5 2 5 5 0 9 5	10/05/93	Japan		X abstract
	WO 03 0 3 0 9 4 3	04/17/03	PCT		X abstract

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					Y	N

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
	Guicheux J. et al., "Apatite as carrier for growth hormone: <i>In vitro</i> characterization of loading and release," <i>Journal of Biomedical Materials Research</i> , Vol. 34, No. 2, (1997), pp. 165-170.
	Gautier H. et al., "In vitro influence of apatite-granule-specific area on human growth hormone loading and release," <i>Journal of Biomedical Materials Research</i> , Vol. 40, No. 4, (1998), pp. 606-613.
	Johnson, O. L., et al., "A month-long effect from a single injection of microencapsulated human growth hormone," <i>NATURE MEDICINE</i> , Vol. 2, No. 7, (July 1996), pp. 795-799.
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					Y	N

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
	Takenaga, M. et al., "A novel insulin formulation can keep providing steady levels of insulin for much longer periods in-vivo", <i>Journal of Pharmacy and Pharmacology</i> , 54: 1189-1194, 2002.
	Takada, S. et al., "Sustained release of human growth hormone from microcapsules prepared by a solvent evaporation technique", <i>Journal of Controlled Release</i> , 88: 229-242, 2003.
	4: NDA 21-075 (not dated).
	Yamaguchi, T. et al., "Ceramic Science Series 7: Bioceramics," GIHODO SHUPPAN Co., Ltd., pp. 7-9, 1984.
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